

PATENT

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REMARKS

In the Final Office Action dated 16th November 2006, claims 3 to 18 are pending of which claims 3 to 18 were rejected.

In particular:

- Claims 3 to 5, 11, 13, 14 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4634420 (Spinosa) in view of US Patent 4314560 (Helfgott et al).
- Claims 6, 8 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of US Patent 4314560 (Helfgott et al) and in view of US Patent 5160319 (Emery).
- Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of Emery and further in view of US Patent 6273877 (West).
- Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 6018676 (Davis).
- Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 5533986 (Mottola).
- Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 3561596 (Knox).
- Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Emery and further in view of Davis.

No amendments to the specification or claims are proposed in this response.

As we have discussed in our previous responses the reference Spinosa discloses an apparatus and method for the removal of tissue from an animal and the particular example is for removal of unwanted organic tissue in the eye. The instrument disclosed in Spinosa includes a needle (14) in Figure 1 which is surrounded by a sheath (42). The needle is vibrated by an ultrasonic

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generator in a handle of the device, the material of the tissue is fragmented by vibration of the needle (column 8 lines 54 – 55) and aspiration of the fragmented tissue occurs through the needle.

This construction is quite different than the construction of the aspiration and flushing needle assembly of the present invention because the present invention uses an outer needle and an internal aspiration cannula which extends through the lumen of the outer needle to the distal end of the outer needle.

We include herewith an affidavit made by Dr. John Allan, a reproductive medicine surgeon practicing at the Wesley Reproductive Medicine & Gynaecological Surgery Unit of The Wesley Hospital, 451 Coronation Drive, Auchenflower Queensland, Australia, a physician who is experienced in the use of aspiration needles for the retrieval of oocytes from the ovaries of a patient. Dr Allan indicates that he has reviewed both the specification of the present invention and the reference Spinoso (US Patent 4634420). He is of the opinion that the device of Spinoso is of such a different construction and operated in a substantially different manner for its purpose of pulverizing eye tissue that the Spinoso device could not be used for the retrieval of oocytes from the ovaries of a patient. He is also of the opinion that the vibration facility of Spinoso would terminally damage an oocyte. He also discusses the importance of being able to separate the device for cleaning and checking purposes and notes that the Spinoso device does not have any arrangement for connecting and separating and as such again would not be useful for the retrieval of oocytes from the ovaries of a patient.

The reference Helfgott describes and teaches a powered hand piece for endophthalmic surgery of the eye. The device has an outer tubular member and an inner tubular coaxial member slidably received within the outer tubular member for linear reciprocation therein (column 6 lines 9 to 14). The outer tubular member has a closed end and a side aperture past which the inner tubular coaxial member slides to sever and remove pieces of vitreous tissue. It

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is noted, too, that there is no lumen between the inner and outer tubular members.

In each case the devices of Spinosa and Helfgott are intended to destroy tissue within the eye of a patient by pulverisation so that it can be removed as a pulp.

In contra-distinction the present invention is directed to a device which is used to remove oocytes or eggs from one of the ovaries of a patient. Oocytes are extremely susceptible to damage during removal and hence must be extremely carefully handled during the extraction procedure as is discussed in the preamble to the specification. For this reason the two main components are separable so that there are no internal obstructions and that a physician can ensure that the components are clean. There is no relative movement between the inner and outer needles during use because such movement may cause damage to the oocytes.

Clearly, one interested in developing an apparatus for the delicate act of oocyte or egg removal would not be motivated to look toward devices for pulverizing unwanted tissue for design suggestions.

It is our submission and as indicated above the opinion of Dr. Allan that neither of the devices of Spinosa and Helfgott would be considered by the physician wishing to extract oocytes from an ovary because too much damage would result to the oocytes. Helfgott in particular does not even have an open end to the outer needle so that the only material which could be aspirated would be a slush through the side aperture.

It is further noted in Spinosa that the needle 14 has a base 56 which is permanently connected into housing 41 by the lugs 47 in the housing fitting into the groove in the base 56. Although the device is shown in an exploded view in Figure 1, it is clearly not intended that the two components, the housing 41 and sheath 42 and the needle assembly 12 be supplied as separate components to the physician to be connected. There is no connection arrangement shown or taught in Spinosa by which a user and particularly a user wearing surgical gloves in a operating theatre, could connect the two

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components. They are supplied connected. As discussed on page 7 lines 19 to 24 of the present application, it is advantageous to supply the aspiration assembly in a dissembled state so that a surgeon or physician can be satisfied that all the components are clean and ready to use before assembling them. This is clearly not possible in Spinoso as the needle would be supplied in the assembly as shown in Figure 2. For these reasons we submit that the examiner is not correct in her statement in paragraph 3 of the Detailed Office Action because Spinoso does not disclose "a separable flushing and aspiration needle".

For these further reasons we submit that neither Spinoso and Helfgott teach or suggest the claimed invention and that claims 3 to 5, 11, 13, 14 and 15 are patentable over these reference taken either separately or in combination.

Claims 6, 8 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of US Patent 4314560 (Helfgott et al) and in view of US Patent 5160319 (Emery) but as these claims all depend from an inventive claim 4 as discussed above, we submit that these claims, too, are inventive.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of Helfgott et al in view of Emery and further in view of US Patent 6273877 (West). Claim 7 specifies that the "the bevelled tip is further sharpened with a secondary bevel to assist with cutting into a follicle. The teaching of West is that a secondary bevel is placed onto the tip of an epidural needle to provide "an adequate degree of blunting to prevent inadvertent damage to the dura matter" (Column 4 lines 42 - 43). The secondary bevel is placed to make the needle blunt rather than to sharpen it as defined in the present claims. Further we submit as this claim depends from an inventive claim 4 as discussed above, we submit that this claim, too, is inventive.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of Helfgott et al in view of US Patent 6018676 (Davis) but as this claim depends from an inventive claim 4 as discussed above, we submit that this claim, too, is inventive.

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Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of Helfgott et al in view of US Patent 5533986 (Mottola) but as this claim depends from an inventive claim 4 as discussed above, we submit that this claim, too, is inventive.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of Helfgott et al in view of US Patent 3561596 (Knox) but as these claims all depend from an inventive claim 4 as discussed above, we submit that these claims, too, are inventive.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of Emery and further in view of Davis but as this claim depends from an inventive claim 4 as discussed above, we submit that this claim, too, is inventive.

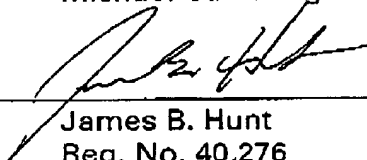
The re-examination and reconsideration of this application is respectfully requested and it is further requested this application be passed to issue.

Although the foregoing discussion is believed to be disposed of the issues in this case, applicant's attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment and remarks.

Respectfully submitted,
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Enclosure:
Affidavit of Dr. John Allan